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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,243	11/21/2001	Jonathan Phillips	32064-5	2400
7590	12/17/2003			EXAMINER
Woodard, Emhardt, Naughton, Moriarty and McNett Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137			PHILOGENE, PEDRO	
			ART UNIT	PAPER NUMBER
			3732	
DATE MAILED: 12/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/990,243	PHILLIPS, JONATHAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pedro Philogene	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 May 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 and 21-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 and 21-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other: \_\_\_\_\_

***Allowable Subject Matter***

Prosecution on the merits of this application is reopened on claims 1-17, 21-30 considered unpatentable for the reasons indicated below:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, line 1 the term "the ratio" lacks prior antecedent basis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7,8,21-23, 26,27,29,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis, Jr. et al (5,354,305).

With respect to claims 1 and 26, Lewis discloses in FIG.3-5, a device comprising an elongated member (10) having a longitudinal axis, a proximal and distal end sections (around 4) and a solid central section (around 12) extending between the proximal and distal fastener receiving areas (14) of greater solid cross-sectional dimensions than the central section, the fastening receiving areas each having at least one hole (24)

extending transverse to the longitudinal axis for receiving a cross fastener adapted to secure to the bone on opposite sides of the elongate member, the proximal and distal end sections thereby providing rigid anchoring locations relative to the central section, the central section providing flexibility, as set forth in column 4, line 26, to promote healing of a fracture. As for the preamble and the functional language limitations regarding the intramedullary nail and fixing a fracture of a long bone, the Lewis device is biocompatible; as set forth in column 4, line 25, and is inherently capable of functioning as a nail; as best seen in FIGS 7-9. Additionally applicant's specification discusses the diameter of the central section being, in general, between 4-7 mm (p. 11, line 20). Lewis discloses in column 4, lines 18-24 a preferable dimension of the device being slightly smaller at about 0.05 inch (about 1.27 mm). As such, the Lewis device is disclosed as inherently capable of at least fixing a fracture of a long bone of a smaller human or animal.

Also regarding the limitation "of greater cross-sectional dimension" in claims 1 and 26 and consistent with page 12, lines 2-7 of applicant's specification discussing the width as a cross sectional dimension, figure 3 shows the cross-sectional width dimension of the end sections is greater than the width dimension of the central section.

With respect to claims 7,8 21, 23, 25, 27, 30, Lewis discloses all the limitations; as set forth in column 4, lines 25,26; and, as best seen in FIGS3-5.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. et al. (5,354,305).

With respect to claim 6, it is noted that Lewis did not teach of a device having a ratio of the fastening areas between 1.3:1, as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach such a ratio, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 2-5, 9,16,17, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, Jr. et al. (5,354,305) in view of Freeland (4,862,883).

With respect to claims 2-5,9, 28, it is noted that Lewis did not teach of a bending device having jaw structure to bend the nail; as claimed by applicant. However, in a similar art, Freeland (FIGS:19-21) evidences the use of a bending device, as taught by applicant, capable of bending an intramedullary nail to allow improved revascularization about the nail.

Therefore, given the teaching of Freeland, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the bending device of Freeland to bend the nail of Lewis to allow improved revascularization about the nail.

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Claims 10-15, 24,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeland (4,862,883) in view of Lewis, Jr. et al. (5,354,305).

With respect to claims 10-15, 24,25, it is noted that Freeland discloses all the method steps, as set forth; except for proximal and distal fastener receiving areas of greater dimension relative the cross sectional dimension of the central section. However, in a similar art, Lewis evidences the use of a nail with a solid cross section and proximal and distal fastener receiving areas of greater dimension relative the cross sectional dimension of the central section to allow the implant to be more easily inserted longitudinally.

Therefore, given the teaching of Lewis, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the shape of the implant of Lewis in the device of Freeland to allow the implant to be more easily inserted longitudinally.

### ***Conclusion***

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene  
December 09, 2003

  
PEDRO PHILOGENE  
PRIMARY EXAMINER